No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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Though one would never know it from respondents' brief, the Leahy-Smith America Invents Act (AIA) worked a sea change in American patent law. Its principal innovation was to replace the first-to-invent system of priority with a first-inventor-to-file regime similar to other major patent systems. A key component of that change was a new definition of prior art. Under that definition, an inventor is entitled to a patent unless "the claimed invention" was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date" of the patent claims. 35 U.S.C. 102(a)(1). The new catch-all provision at the end of that list informs the meaning of the terms that precede

it, clarifying that a sale qualifies as prior art only if it makes the claimed invention available to the public.

Respondents' effort to oppose that conclusion is most notable for what it does not include. Respondents make no effort to defend, and in fact run away from, the reasoning of the decision below. Respondents do not attempt to explain how their construction of Section 102(a)(1) fits into the broader context of the AIA. And respondents offer no answer to this Court's cases interpreting statutes with strikingly similar catch-all provisions.

Respondents instead argue that Congress was not sufficiently explicit when it amended the pre-AIA on-sale bar. But it is not easy to imagine how Congress could have more clearly conveyed its intended meaning. Every relevant indicator—the text, the structure, the legislative history, and the underlying policy—supports petitioner's interpretation. Respondents' interpretation has only one thing in common with the Federal Circuit's: it badly misconstrues the AIA. The Federal Circuit's judgment should be reversed.

A. The Plain Text Of 35 U.S.C. 102(a)(1) Requires That A Sale Make The Claimed Invention Available To The Public

1. The Catch-All Provision In Section 102(a)(1) Clarifies The Meaning Of 'On Sale'

a. Section 102(a)(1) lists three categories of patent-defeating prior art. The first two are "patented" and "described in a printed publication." The third category of prior art—set off by a comma and the word "or"—is a three-item list. That list consists of enumerated categories, followed by a catch-all category beginning with the word "otherwise." Construing statutes with that structure, this Court has repeatedly relied on the "familiar canon of statutory construction" that each enumerated

item "must be read in light of the final, comprehensive category." *Federal Maritime Commission* v. *Seatrain Lines, Inc.*, 411 U.S. 726, 734 (1973); *Paroline* v. *United States*, 572 U.S. 434, 447 (2014).

Respondents do not identify a single instance in which this Court, construing a similarly structured statute, has reached a different conclusion. That is unsurprising. As petitioner has explained, a term such as "otherwise" "relat[es] to and defin[es]" the language that immediately precedes it. *United States* v. *Standard Brewery*, 251 U.S. 210, 218 (1920). That rule is in line with the plain meaning of the word "otherwise": "in a different way or manner." *Merriam-Webster's Collegiate Dictionary* 879 (11th ed. 2009). And it honors the venerable *noscitur a sociis* canon, under which words in a statute are "known by the company [they] keep[]." *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 575 (1995).

b. Respondents' efforts to undercut *Seatrain Lines* and *Paroline* (Br. 34-37) cannot withstand scrutiny. Respondents' first argument—that those cases are inapt because, in each instance, "Congress created the entire list [of statutory terms] at once" (Br. 34)—requires little response. It is irrelevant when Congress added various constituent parts to the statute, because the Court's ultimate task is "simply [to] interpret the statute as written." *Arthur Andersen LLP* v. *United States*, 544 U.S. 696, 705 (2005).

Respondents next argue that interpreting the statute in accordance with *Seatrain Lines* and *Paroline* would create "hopeless redundancies" between "in public use" and the catch-all provision. Br. 35-36. As petitioner has explained, however, some courts had interpreted the pre-AIA public-use bar, much like the pre-AIA on-sale bar, to reach uses that did not make claimed inventions available to the public. See Pet. Br. 43 (collecting cases). The catch-

all provision thus makes clear that a public use, like a sale, is prior art only if it satisfies that requirement.

Respondents do not dispute petitioner's interpretation of pre-AIA precedent on the public-use bar. Instead, they assert that Congress could not have added the catch-all provision to clarify "in public use" because it was initially introduced in a draft bill that deleted the phrases "in public use" and "on sale," and that petitioner's interpretation would make the catch-all provision "modify different preexisting categories differently." Br. 36.

Those assertions lack merit. As to the former: it is the final, enacted text that matters. See *Arthur Andersen*, 544 U.S. at 705. And under this Court's approach in *Seatrain Lines* and *Paroline*, the catch-all provision—as it appears in the final, enacted text—informs the meaning of "public use."

As to the latter assertion: respondents misunderstand the structure of the statute. Section 102(a)(1) contains a three-category, disjunctive list. After the second category—"described in a printed publication"—there is a comma, the word "or," and a third category. The third category contains three subcategories: "in public use, on sale, or otherwise available to the public." Because the catch-all phrase falls within the third category, it directly operates only on the two subcategories that precede it. And it operates on each of those subcategories in exactly the same way: *viz.*, by clarifying that uses and sales qualify as prior art only if they make the claimed invention "available to the public."

Respondents further argue that, under petitioner's interpretation, the catch-all provision will "in substance read several categories out of the statute." Br. 36. That is so, they say, because no litigant would ever try to establish the elements of the on-sale bar if it could simply prove that the claimed invention was available to the public and

thus fell within the ambit of the catch-all provision. See Br. 36-37.

As a preliminary matter, respondents' concern would apply equally to both parties' interpretations. Respondents interpret "patented," "described in a printed publication," and "in public use" as "inherently requir[ing] public availability." Br. 32. If that is true, a litigant could potentially proceed under the catch-all provision whenever it is unable to satisfy the specific requirements of any of those enumerated categories—each of which has a relevant body of case law construing it. See, *e.g.*, *Blue Calypso, LLC* v. *Groupon, Inc.*, 815 F.3d 1331, 1347-1351 (Fed. Cir. 2016) (discussing "printed publication" requirement).

In fact, respondents' concern is illusory. As the government explains, "Section 102(a)(1) contemplates two distinct senses in which an invention may be placed in the public domain." U.S. Br. 16. When an invention is "patented" or "described in a printed publication," the inventive *idea*" is placed in the public domain. *Ibid.* By contrast, when an invention is "in public use," it is "the *physical embodiment* of the invention" that has entered the public domain. *Id.* at 17-18. Without retention of "in public use" or "on sale," the statute would simply read: "patented, described in a printed publication, or otherwise available to the public." In that circumstance, the statute might be read to imply that the catch-all provision was limited to alternative means of making the inventive idea—not the physical embodiment of the invention—publicly available. See *Gustafson*, 513 U.S. at 573-575. Congress foreclosed such an argument by including "in public use" and "on sale."

c. Respondents' remaining arguments concerning the catch-all provision lack merit.

Respondents contend that the word "otherwise" "serves to acknowledge the * * * overlap between the

new category and the old ones, and to clarify that the catchall category captures methods of public disclosure not previously described." Br. 31. But that is just a fancy way of saying that "otherwise" does no work. Without "otherwise," there would still be the possibility of overlap between "in public use," "on sale," and "available to the public." And it is self-evident that "available to the public" captures activities other than public uses and sales. See *Loughrin* v. *United States*, 134 S. Ct. 2384, 2390 (2014).

That "otherwise" does no work in respondents' interpretation is reason enough to reject it. But there is a second, more fundamental flaw: respondents refuse to acknowledge any relationship between the catch-all category and the preceding enumerated categories. As this Court has long recognized, a catch-all category not only reaches "other devices not specifically enumerated," *Federal Maritime Board* v. *Isbrandtsen Co.*, 356 U.S. 481, 492 (1958), but "limit[s] * * * the specifically enumerated categories as well," *Seatrain Lines*, 411 U.S. at 734. Accordingly, the enumerated categories "must be read in light of the final, comprehensive category." *Ibid.*

In an effort to avoid the latter function of the catch-all provision, respondents offer two examples. Br. 32. Neither is illuminating. Respondents first posit an individual saying: "I'd like to go see the Astros, the Dodgers, the Red Sox, the Orioles, or any other first-place team." *Ibid.* That example, however, implies the Orioles are not in first place only because the Red Sox and the Orioles are in the same division and thus cannot both be in first. If the individual instead said, "I'd like to go see the Astros, the Dodgers, the Red Sox, *the Brewers*, or any other first-place team," it would indeed imply that each of the listed teams was in first place—at least if the individual were speaking grammatically. See *Paroline*, 572 U.S. at 447; *Seatrain Lines*, 411 U.S. at 734.

Respondents' second example, drawn from *Barnhart* v. *Thomas*, 540 U.S. 20 (2003), is simply a poor fit here. The Court in *Barnhart* posited parents telling a child: "You will be punished if you throw a party or engage in any other activity that damages the house." 540 U.S. at 27. But here, the question is not whether a phrase modifying a proximate antecedent ("any other activity") reaches back and modifies another ("a party"). The rule of the last antecedent is inapplicable here; the relevant question is whether a catch-all category that is *parallel* to preceding enumerated categories informs the meaning of those categories. Under this Court's precedents, the answer to that question is yes. See *Paroline*, 572 U.S. at 447; *Seatrain Lines*, 411 U.S. at 734.

d. Beyond the catch-all provision, the broader structure of Section 102(a)(1) supports petitioner's interpretation under the *noscitur a sociis* canon. Respondents' attacks on that canon (Br. 33-34) miss the mark.

Respondents first argue (Br. 33) that the *noscitur a sociis* canon does not apply because the phrase "on sale" unambiguously does not require public availability. That is manifestly incorrect. As the government explains in its amicus brief, "on sale" "inherently suggests a sale or offer to sell *to the public*." U.S. Br. 15 (emphasis added). At a minimum, the phrase "on sale" is "susceptible of multiple * * * meanings." *United States* v. *Williams*, 553 U.S. 285, 294 (2008). And if that is true, this is the archetypal case in which the *noscitur a sociis* canon can be used to align the phrase with the "neighboring words with which it is associated." *Ibid.*

Respondents next note (Br. 33-34) that Congress adopted the categories of prior art in the AIA's definition at different times. But respondents cite no case in which this Court has refused to apply the *noscitur a sociis* canon for that reason, and petitioner is unaware of any such

case. That is unsurprising; as petitioner has already explained, it is the final, enacted text that matters to the textual analysis. See *Arthur Andersen*, 544 U.S. at 705.

Respondents suggest that Section 102(a)(1) is a "disjunctive list of items that are each quite distinct from the other no matter how construed." Br. 34 (internal quotation marks and citation omitted). Wrong again. Across its three categories, Section 102(a)(1) identifies five types of prior art. Four of the five, according to respondents, "connote availability to the public." Br. 32. And the one that supposedly does not imply public availability—"on sale"—shares a policy rationale with other categories of prior art: namely, "[a] similar reluctance * * * to remove existing knowledge from public use." See *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 64 (1998). The on-sale bar thus does not "have a character of its own," so as "not to be submerged by its association" with the other types of prior art in Section 102(a)(1). *Russell Motor Car Co.* v. *United States*, 261 U.S. 514, 519 (1923). The *noscitur a sociis* canon applies with full force to the phrase "on sale" and confirms petitioner's interpretation of it.

2. *Respondents' Reliance On The Doctrine Of Congressional Ratification Lacks Merit*

In response to petitioner's textual argument, respondents make no effort to defend the reasoning of the decision below. And respondents abandon their reliance on the rule of the last antecedent, a key component of their argument until now.

Respondents instead put their eggs in one textual basket. Respondents contend that the phrase "on sale" "had become a term of art" by the time of the AIA, having been construed in various decisions. Br. 25 (internal quotation marks and alterations omitted). And they further contend

that Congress intended to ratify those decisions, and retain that meaning, when it enacted the AIA. See Br. 25-29. The doctrine of congressional ratification has two elements: (1) Congress must "reenact [the relevant statutory language] without change," and (2) the "supposed judicial consensus [must be] so broad and unquestioned that [the Court] must presume Congress knew of and endorsed it." *Jama* v. *Immigration & Customs Enforcement*, 543 U.S. 335, 349 (2005). Respondents cannot satisfy either element.

To begin with, Congress did not reenact the relevant statutory language without change. To the contrary, when it enacted the AIA, Congress made a series of changes that have a substantial effect on the meaning of "on sale." First and foremost, Congress added "otherwise available to the public." But Congress also added the defined term "claimed invention," 35 U.S.C. 100(j), and removed the geographic limitation on the on-sale bar. And it shifted from a first-to-invent system to a first-inventor-to-file system. Because all of those changes bear on the meaning of "on sale," the congressional-ratification doctrine simply does not apply. See, *e.g.*, *Holder* v. *Martinez Gutierrez*, 566 U.S. 583, 593 (2012).

In any event, there was no broad and unquestioned judicial consensus before the AIA that the phrase "on sale" reached sales that did not make inventions available to the public. Respondents' hyperbolic assertion (uncritically parroted by their amici) that their interpretation aligns with "nearly two centuries" of the Court's case law (Br. 6), starting with *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1 (1829), is incorrect. In *Pennock*, the Court considered language in the 1793 Patent Act permitting the patenting of subject matter that was "not known or used before the [patent] application." *Id.* at 18. The Court read that language to mean "not known or used *by the public*, before

the application." *Id.* at 19 (emphasis added). That is because prior art was meant to address a situation in which an inventor "put [the invention] into public use[] or s[old] it for public use before he applie[d] for a patent." *Id.* at 23. *Pennock* thus made clear that the relevant uses and sales were ones that put inventions into the public domain.

The Court's more recent decisions are to the same effect. The Court echoed *Pennock* in *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), which construed pre-AIA law to "exclude from consideration for patent protection knowledge that is *already available to the public*." *Id.* at 148 (emphasis added). "[O]n sale" thus included any "public sale" that "placed [the invention] in public commerce." *Id.* at 149. Most recently, in *Pfaff*, the Court reiterated that the on-sale bar prevents an inventor from "remov[ing] existing knowledge from public use." 525 U.S. at 64. "For nearly two centuries," therefore, the Court has actually focused on sales that make the claimed inventions available to the public—on the theory that subsequent patents on those inventions would take away what the public already has.

To be sure, as respondents note (Br. 7-9), some lower-court decisions—mostly from the Federal Circuit—stood in tension with the decisions of this Court and seemingly extended the pre-AIA on-sale bar to sales that did not make the claimed inventions available to the public. It is unclear whether those cases were correctly decided in light of the structure of the pre-AIA on-sale bar. See U.S. Br. 15-18. But even if Congress had not made fundamental changes in the AIA that affect the meaning of "on sale," the doctrine of congressional ratification would not apply, because those cases do not give rise to the requisite "broad and unquestioned" "judicial consensus." *Jama*, 543 U.S. at 349.

In a related vein, respondents suggest (Br. 28) that Congress could have changed the meaning of "on sale" in a different—and, to their minds, clearer—way. But even when this Court has definitively interpreted a statute in a certain manner—again, not the case here—Congress can alter that interpretation by providing a "relatively clear indication of its intent in the text of the amended provision." *TC Heartland LLC* v. *Kraft Foods Group Brands LLC*, 137 S. Ct. 1514, 1520 (2017). Congress did just that in the AIA when it added a new catch-all category based on public availability and linked it to the two preceding enumerated subcategories with the word "otherwise." Given the Court's interpretations of other similarly structured statutes, see pp. 2-3, *supra*, Congress's changes to the AIA provide a crystal clear, not just "relatively clear," indication of its intent.

What is more, the hypothetical, "clearer" alternatives respondents propose (Br. 28) are unpersuasive. Two of respondents' alternatives, "on sale publicly" and "publicly on sale," would function differently from the catch-all provision, because they imply only that the *fact* of the sale must be public—not that the sale must put the claimed invention into the public domain. And while respondents' third alternative, "on sale to the public," would affect the meaning of "on sale" in the same way as "otherwise available to the public," it would not also reach new forms of prior art not covered by the existing enumerated categories. The language Congress used is thus fit for purpose: it simultaneously informs the meaning of "on sale" and extends the reach of Section 102(a)(1).

3. Section 102(b)(1) Does Not Support Respondents' Interpretation

Reprising an argument they pressed below, respondents contend (Br. 37-39) that the phrase "public disclosure" in Section 102(b)(1)(B) is "surplusage" under petitioner's interpretation because a "disclosure" in Section 102(b) is necessarily "public" by virtue of Section 102(a)(1). That argument is both confusing and incorrect.

Section 102(b)(1) creates a one-year grace period during which "[a] disclosure * * * of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1)." All agree that "disclosure" in that sentence refers to a "prior art event" under Section 102(a)(1). The grace period in Section 102(b)(1) applies in two separate circumstances. The first is when the disclosure—that is, the Section 102(a)(1) "prior art event"—was made by the inventor. 35 U.S.C. 102(b)(1)(A). The second is when a third party makes the disclosure, as long as "the subject matter disclosed had * * * [*earlier*] been publicly disclosed by the inventor." 35 U.S.C. 102(b)(1)(B).

Respondents suggest that petitioner "cannot explain why Congress needed to clarify that the earlier disclosure must be 'public' if all Section 102(a) disclosures are necessarily public." Br. 39. Petitioner has already done so. See Pet. Br. 44-45. To reprise: Section 102(b)(1) refers to two distinct transmissions of information: (1) "[a] disclosure * * * of a claimed invention" (*i.e.*, the "prior art event"), and (2) a separate, earlier disclosure of "the subject matter [later] disclosed." The statute specifies that "disclosure * * * of a claimed invention" is an act that falls within the ambit of Section 102(a)(1). Such an act is necessarily public under petitioner's interpretation of Section 102(a)(1). But the statute does not specify anything about the earlier disclosure of the "subject matter." Enter "publicly." That word, as it appears in Section 102(b)

(1)(B), makes clear that "the subject matter disclosed" falls within the ambit of the provision only if the earlier disclosure of the subject matter is itself public.

That only makes sense. Suppose that an inventor tells a friend about an invention in private. After that conversation, but before the inventor makes a disclosure that would qualify as prior art under Section 102(a)(1), a third party independently discloses the same invention. Without the word "publicly," the inventor could argue that the third party's disclosure does not constitute prior art (and thus is no impediment to the inventor's obtaining a patent) simply because the inventor had already "disclosed" the "subject matter" to a friend. That, of course, would be inconsistent with Section 102(a)(1). Congress avoided that result by including "publicly" before "disclosed" in Section 102(b)(1)(B).

B. The Legislative History Of The AIA Supports The Plain-Text Interpretation

As petitioner has explained, the legislative history of the AIA demonstrates that Congress intended to make clear that the sale of a claimed invention qualifies as prior art only if it makes the invention available to the public. Respondents largely ignore the authoritative committee reports that manifest that intention. Instead, they invoke a "general recognition," pieced together from the drafting history of bills that Congress abandoned, that Congress did not intend to require that all prior-art sales make a claimed invention publicly available. Br. 44. That is the epitome of "entering a crowded cocktail party and looking over the heads of the guests for one's friends." *Conroy* v. *Aniskoff*, 507 U.S. 511, 519 (1993) (Scalia, J., concurring). To the extent the Court feels moved to consider it, the legislative history supports petitioner's interpretation.

1. As this Court has repeatedly explained, committee reports represent the "considered and collective understanding of those [members of Congress] involved in drafting and studying proposed legislation" and are "the authoritative source for finding the Legislature's intent." *Garcia* v. *United States*, 469 U.S. 70, 76 (1984). Here, the committee reports unambiguously show that Congress intended to eliminate sales that do not make claimed inventions available to the public as prior art.

According to the House Judiciary Committee's report on the bill that became the AIA, the purpose of the catch-all provision was to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 42-43 & n.20 (2011). The House Report went on to cite Senate floor statements from March 8 and 9, 2011. Those floor statements included Senator Kyl's statement that the catch-all provision "limits all non-patent prior art to that which is available to the public," *ibid.* (citing 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011)), and Senator Leahy's comment that "subsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art," *ibid.* (citing 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011)).

For its part, the Senate Judiciary Committee, which first added the phrase "otherwise available to the public," explained that the catch-all provision was intended to "emphasize the fact that [prior art] must be publicly available." S. Rep. No. 259, 110th Cong., 2d Sess. 9 (2008). And it specified that the catch-all provision was designed to "make clear that secret collaborative agreements, which are not available to the public, are not prior art." *Id.* at 39.

In the face of those reports, respondents offer conspicuously weak answers. In an interpretive move similar to the Federal Circuit's below, respondents discount the House Report because it does not use the words "on sale." Br. 45. But the House Report expresses the overarching intent to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, *supra*, Pt. I, at 43. And it cites floor statements making clear that "*all* nonpatent prior art," plainly including sales, must make a claimed invention "available to the public." *Id.* at 43 & n.20 (emphasis added).

Respondents further suggest that the "secret collaborative agreements" cited in the Senate Report must refer to something other than the kind of arrangement petitioner had with MGI. S. Rep. No. 259, *supra*, at 39. The text of the report, however, explains precisely what the Senate committee, like the House committee, meant: the catch-all provision was intended to "emphasize the fact that [prior art] must be publicly available." *Id.* at 9.

Respondents are left to argue that the committee reports "cannot overcome" the drafting history of other unenacted bills. See Br. 45. But that gets it exactly backward. This Court has repeatedly noted that committee reports are the most reliable form of legislative history. See, *e.g.*, *Garcia*, 469 U.S. at 76.

2. Instead of meaningfully engaging with the committee reports, respondents meander through the drafting history of unenacted predecessor bills. See Br. 40-43. They observe that Congress considered eliminating the on-sale bar altogether and suggest that, because Congress did not do so, it must have intended to retain the on-sale bar as it existed before the AIA. Far from doing away with the on-sale bar, however, the AIA "preserves the substantial body of law on other aspects of the on-sale bar

while clarifying that a sale must make the claimed invention publicly available in order to qualify as prior art." Pet. Br. 30 (citing Markup of H.R. No. 1249, House Committee on the Judiciary, at 101 (Apr. 14, 2011)). Thus, the AIA's new definition of prior art incorporates elements of established on-sale and public use jurisprudence, such as the "ready for patenting" requirement, *Pfaff*, 525 U.S. at 67, and the "experimental use" exception, *City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126, 135 (1877).

Respondents' drafting-history narrative only bolsters that interpretation. The statement respondents emphasize from Representative Lofgren illustrates the point. In 2011, the House Judiciary Committee (of which Representative Lofgren was a member) considered an amendment that would have replaced "in public use, on sale, or otherwise available to the public" with "otherwise disclosed to the public." Br. 11-12. Representative Lofgren expressed "concern[] about the deletion of specific categories of prior art with well-established meanings in case law." Br. 12, 43. In response, the committee reverted to the previous formulation, which was then enacted. In the House Report, Representative Lofgren offered views on other aspects of the final bill but did not express disagreement with the committee's conclusion that prior art "must be publicly accessible." H.R. Rep. No. 98, *supra*, at 43, 163-65.

3. Respondents' emphasis on certain statements by Senator Kyl years before the AIA's enactment (Br. 11, 41-43) is similarly misguided. Citing Senator Kyl's concern that retaining the phrase "on sale" might not eliminate so-called "secret sales," respondents accuse Senator Kyl of attempting to "create[] his preferred" meaning through his later floor statement. Br. 43. That is wild speculation. It is more likely that Senator Kyl was persuaded by other

legislators who—like both Judiciary Committees in their official reports—took the position that Section 102(a)(1) as enacted achieved that end. See Pet. Br. 7-8, 25-30. Senator Kyl's ambiguous statements, made years before Congress enacted the AIA, are not reliable gauges of congressional intent.

C. The Structure Of The AIA Further Supports The Plain-Text Interpretation

As petitioner has explained, the AIA fundamentally changed the American patent system and brought our Nation's patent laws in line with other major patent systems around the world. Petitioner's interpretation of Section 102(a)(1) is consistent with the broader structure of the AIA; respondents' is not.

Respondents first contend (Br. 49-50) that, under petitioner's interpretation, inventors will keep their inventions secret and pursue profits, rather than seeking a patent monopoly under the first-inventor-to-file system. That prediction is unrealistic. Even if an invention were "easily concealable," see Br. 49, choosing not to file a patent application would present a serious risk under the AIA. Simultaneous (or near-simultaneous) invention is a common phenomenon, because inventors often recognize (and set out to fix) a problem at the same time. An inventor who keeps an invention secret for too long risks losing his patent rights altogether if another inventor identifies the issue and files an earlier patent application. The first-inventor-to-file system thus "encourages the prompt filing of patent applications." S. Rep. No. 259, 110th Cong., 2d Sess. 7 (2008).

Respondents insist that their interpretation would not conflict with the AIA's new post-grant-review procedure, because "challengers who institute post-grant review based on a sale must have the grounds in hand, *without*

discovery." Br. 51. Under respondents' interpretation, however, a party could make a colorable allegation that a secret sale had taken place, but could still need burdensome discovery to substantiate its claim in the face of the patentee's contrary arguments. Such discovery is ill-suited to the expedited nature of post-grant-review proceedings. See 35 U.S.C. 326(a)(5), (6), (11). That is presumably why Congress limited post-grant-review proceedings to patents governed by the AIA and its revised definition of prior art. Congress's adoption of the post-grant-review procedure further underscores why respondents' interpretation cannot be correct.

D. The Plain-Text Interpretation Better Serves The Broader Purposes Of The AIA And The Patent System

Petitioner's interpretation of Section 102(a)(1) is also consistent with the purposes underlying the patent system. In particular, such a requirement preserves the fundamental *quid pro quo* of patent law, promotes predictability in the patent system, and ensures that small inventors are on equal footing with their larger counterparts. Respondents do not address any of those arguments, and the arguments they do make about the purposes of the patent system lack merit.

1. Respondents contend that petitioner's interpretation would flout the purposes of the patent system by leading to "rampant pre-patenting commercialization" through nondisclosure agreements. Br. 46. Those concerns are overblown. To begin with, petitioner has never suggested that a nondisclosure agreement—without more—would necessarily exclude a sale from the on-sale bar. For example, if a company offered a product to all comers but on the condition that purchasers sign non-disclosure agreements, a court could well conclude that the product was "on sale" and "available to the public." That

hypothetical situation, however, is a far cry from petitioner's pre-FDA-approval sale to a single entity, MGI, which is not an ultimate purchaser. See U.S. Br. 26-30. And it raises the question of what "available to the public" means, which is not properly at issue in this case.

Respondents, moreover, concede (Br. 58-59) that certain forms of "pre-patent commercialization"—for example, the funding of development costs in exchange for future profits—would not qualify as prior art even under their construction of the on-sale bar. That is impossible to square with respondents' contention that pre-patent commercialization starts the on-sale clock. This case illustrates the point. In respondents' view, petitioner could have sold a right to future profits in exchange for $11 million in capital without triggering the on-sale bar. But because petitioner obtained the same $11 million by selling a future right to *distribute its product*—if approved by FDA—it made a prior-art sale. See, *e.g.*, Br. 1. That is an absurdly fine distinction. And it shows that Congress had a purpose other than preventing pre-patent commercialization in mind when it included "on sale" in the AIA: namely, to treat sales that make inventions available to the public as prior art.

2. Respondents also contend (Br. 47-48) that petitioner's interpretation would create an effectively unlimited period of exclusivity for process patents. In the case of process patents, however, the AIA provides still further incentive to avoid delay. The AIA dramatically expanded the "prior user rights" defense, which permits an entity that made commercial use of an invention more than one year before another sought a patent on it to continue using the invention without liability for infringement. See 35 U.S.C. 273. Under pre-AIA law, that defense was limited to business-method patents and to the individuals who actually performed the patented method. See 35

U.S.C. 273(a)(3) (1999). Under the AIA, however, the defense is now available to essentially all process patents that are commercially viable and to anyone (or any entity) with control over the individual performing the patented method. See 35 U.S.C. 273(a), (e)(1).

That change directly responds to respondents' concern that, under petitioner's interpretation, parties will have virtually unlimited exclusivity for process patents that are difficult to reverse-engineer. Under the AIA, an inventor has an incentive to patent its process as soon as possible, even if the inventor's use of the process is secret, so that it can extinguish its competitors' prior-user rights.

3. Respondents further contend (Br. 48-49) that petitioner's interpretation would effectively abrogate the rule that an offer for sale can trigger the on-sale bar. That is incorrect. Just as a sale to the public would constitute prior art, so too would an offer of sale to the public—say, in a newspaper advertisement. Such an offer would make the claimed invention "available to the public" in a way that petitioner's sale to a single entity did not.

E. Respondents Have Forfeited Any Argument That Petitioner's Claimed Invention Was Available To The Public

In the district court, respondents argued that petitioner "violated the on-sale bar even under [its] proposed interpretation of the AIA." Pet. App. 151a. After losing in the district court, however, respondents made the strategic decision not to pursue that argument on appeal in the Federal Circuit. They have thus forfeited any argument that the sale to MGI somehow made the claimed invention "available to the public" under the AIA.

Respondents barely even try to rebut that conclusion. In a footnote, respondents contend that they "consistently argued" that petitioner's sale made the invention availa-

ble to the public. Br. 53 n.11. That is flat wrong. Tellingly, the only citations respondents offer in support of that proposition are to the (pre-forfeiture) opinion *of the district court* and their (post-forfeiture) brief in opposition to certiorari *in this Court*. What matters is what happened between those filings—*viz.*, respondents' strategic decision not to pursue that argument *in the Federal Circuit*.

Respondents' contention that petitioner's forfeiture argument "rests entirely" on the government's Federal Circuit brief is frivolous. Br. 53 n.11. Petitioner cited the government's brief merely as evidence that the argument was not in play in the Federal Circuit. See Pet. Br. 24 n.3. After the government filed its brief noting that respondents were not raising the argument, respondents said nothing to refute that contention in further Federal Circuit proceedings—whether in their reply brief or at oral argument. That is because respondents had in fact jettisoned the argument. Respondents may regret that decision now, but it is too late.

Finally, even if the Court were to blow through respondents' forfeiture and reach the merits of their case-specific and fact-bound argument, petitioner should still prevail. Petitioner's sale to a single entity, MGI, did not make the claimed invention "available to the public." MGI was bound to (and did) keep petitioner's proprietary knowledge related to the claimed invention confidential. See Pet. Br. 9. MGI could not do anything with the product embodying the claimed invention until the Food and Drug Administration approved the product and petitioner manufactured it. See *ibid.* And MGI was not the ultimate purchaser of the product. See *ibid.* If those facts were sufficient to make a claimed invention "available to the public," any sale or offer for sale would qualify.

Respondents cannot avoid the public-availability requirement by simply neutering it. Because the AIA requires that a sale make the claimed invention available to the public, and because respondents have forfeited any argument that the sale at issue here satisfied that requirement, this Court should reject the Federal Circuit's now-undefended reasoning and reverse its indefensible judgment.

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The judgment of the court of appeals should be reversed.

Respectfully submitted.

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